STANDARD OPERATING PROCEDURE FOR VERIFICATION SERVICES FOR CHILD NUTRITION LABELED PRODUCTS

PURPOSE

The purpose of this instruction is to set forth a procedure for verification services used to determine product compliance for the Child Nutrition (CN) Labeling Program.

POLICY

The U.S. Department of Agriculture (USDA), Food and Nutrition Service (FNS) has delegated authority to the Agricultural Marketing Service (AMS) and U.S. Department of Commerce (USDC), National Marine Fisheries Service (NMFS) to verify product compliance for the CN Labeling Program. This delegation of authority is intended to ensure manufacturers properly apply and document effective procedures to monitor and control the production of their CN products. All manufacturers participating in the CN Labeling Program are required to have a QC program[1] (Appendix C in 7 CFR §§ 210, 220, 225 and 226) per Memorandum of Understanding between USDA, FNS, AMS, Food Safety and Inspection Service and USDC, NMFS.

SCOPE

AMS/NMFS will verify the implementation of a manufacturer's CN QC Program. AMS and NMFS will offer manufacturers two options to determine product compliance for the CN Labeling Program. These options are the CN Quality Control Verification Program (QCVP) or CN In-plant Monitoring Program (IMP) [1]. For these services, AMS will charge manufacturers as predetermined by the AMS program performing the CN product review.

DEFINITIONS

1. Critical non-conformance - A deviation from specifications as outlined in the manufacturer's approved QC Program which will affect the product's contribution to the meal pattern requirements.

2. Non-critical non-conformance - A deviation from specifications as outlined in the manufacturer's approved QC Program which is not likely to affect the product's contribution to the meal pattern requirements.

3. Satisfactory rating - A facility scores no more than three (3) non-conformances, of which none is a critical non-conformance (see table 1).

4. Conditional rating - A facility scores no more than seven (7) non-conformances, of which only one may be a critical non-conformance (see table 1).

[1] CN Labeled juice and juice drink products are produced under AMS regular in-plant inspection.

5. Unsatisfactory rating - Anything that fails to meet the requirements for a conditional facility rating (see #4 above and table 1).

6. Reduced frequency - CN product reviews are conducted semi-annually (approximately every 6 months).

7. Normal frequency - CN product reviews are conducted quarterly (approximately every 3 months).

8. Tightened frequency - CN product reviews are conducted during the next CN product run or within 30 days (see follow-up visit).

9. Follow-up visit - When a critical non-conformance is detected, a follow-up visit will be conducted at the next CN product run or within 30 days at the discretion of AMS/NMFS representative. Manufacturers who do not produce monthly will be required to have a follow-up visit during their next scheduled CN product run.

10. Corrective Action - An action to eliminate the cause of a detected non-conformance.

FACILITY RATING SYSTEM

The AMS and NMFS representative will assign manufacturers a facility rating after each CN product review, for both verification services (IMP and QCVP). A manufacturer's rating is based on their ability to implement processing and monitoring procedures as outlined in their QC manual (see Table 1).

Table 1 - Facility Rating System

Rating Levels	Total critical non-conformances allowed	Total non-conformances allowed
Satisfactory	0	3
Conditional	1	7
Unsatisfactory	Fails to meet conditional	

REVIEW FREQUENCY

Manufacturers participating in the QCVP will begin CN product reviews at a normal frequency level and are required to have a minimum of four unannounced reviews (quarterly). Manufacturers who do not produce CN labeled product(s) quarterly will be required to have a minimum of two product reviews per year. The number of reviews may increase or decrease based on the manufacturer's facility rating/performance.

Manufacturers who receive a satisfactory facility rating on four (4) consecutive CN product reviews will qualify for reduced frequency (see Table 2). Manufacturers who continue to receive a satisfactory rating will remain on a reduced frequency review.

Table 2 - Frequency of Review

Facility Review Level	Frequency	Criteria
Reduced	Semi-annually	• Must continue to receive Satisfactory facility rating to remain at Reduced frequency • Switch to Normal frequency if facility receives Conditional rating • Switch to Tightened frequency if facility receives an Unsatisfactory rating
Normal	Quarterly	• Must earn Conditional or Satisfactory facility rating to remain at Normal frequency (Conditional facility rating due to a critical non-conformance must be addressed within 5 business days) • Switch to Reduced frequency if facility receives 4 consecutive Satisfactory ratings • Switch to Tightened frequency if facility receives an Unsatisfactory rating
Tightened	See follow-up visit	• Switch to Normal frequency if facility receives a Satisfactory rating • 2 consecutive Unsatisfactory facility rating results in FNS notification

Manufacturers who receive a conditional facility rating due to a critical non-conformance must document corrective actions and submit responses in writing within 5 business days to the appropriate AMS or NMFS representative. The AMS/NMFS representative will verify corrective actions, which may include a follow-up visit (see # 9 above) to confirm corrective actions were implemented (see table 3 for rating procedural flow). Failure to respond and correct critical non-conformances within the allotted time will result in an unsatisfactory facility rating.

Manufacturers who receive an unsatisfactory facility rating must document corrective actions and submit responses in writing within 5 business days to the appropriate AMS or NMFS representative. The facility will be subject to a follow-up visit (see #5 above) and a full CN product review will be conducted. If the follow-up visit results in a conditional facility rating the manufacturer will be placed on tightened frequency until the facility receives a satisfactory rating. If a follow-up visit results in an unsatisfactory facility rating, the Food and Nutrition Service (FNS) will be notified. FNS will coordinate with AMS CN Labeling Operations Office

and take the appropriate actions, which may include rescinding CN label(s), submitting the manufacturer name to FNS regional and state offices for labeling violation or removing the manufacturer from the CN Labeling Program (see table 3 for rating procedural flow).

It is the responsibility of the manufacturer to halt production, divert product to non-CN, or restrict shipment of product when a critical non-conformance is detected. The manufacturer will be permitted to continue CN production after appropriate corrective actions are implemented and confirmed by an AMS or NMFS representative. Normal frequency will resume after receiving a satisfactory facility rating.

PROCEDURES

The IMP will require the appropriate agency's grading/inspection service to monitor all shifts of production of CN labeled product(s). Once a manufacturer's QC program has been approved under the IMP option, the firm's facility may be subject to an initial validation assessment. The QCVP will verify a manufacturer's ability to meet requirements as written in the manufacturer's QC program.

1. Key Elements of In-Plant Monitoring Program (IMP)

    a) Requires an AMS/NMFS representative to be present to monitor all shifts of production of CN labeled product(s).

    b) The AMS representative may perform CN associated quality control checks (which may include weighing, sampling etc.) at the manufacturer's request. However, the manufacturer is still required to have an approved QC program.

2. Key Elements of Quality Control Verification Program (QCVP)

    a) Require a thorough review of records by AMS or NMFS representative to ensure the manufacturer is properly monitoring and controlling their CN labeled product(s) as outlined in the approved QC program.

    b) Observe at least one CN production run. If a manufacturer is unable to produce CN product during their scheduled CN product review due to unforeseen circumstances (such as, but not limited to equipment failure, problem with shipment, etc.), the AMS/NMFS representative shall observe a production run similar to a CN product when possible. Such situations should be rare; however, if the AMS/NMFS representative notices a repeated occurrence, the respective National Office should be contacted through the appropriate channels.

3. Changing Verification Program

    Manufacturers may request to change their verification option at any time; however this change must be approved by an AMS/NMFS Approving Official prior to production under

the revised program. Manufacturers who initially selected the IMP option and decide to switch to the QCVP option may be required to revise their QC Program to update title(s) of personnel particularly if an AMS representative was identified as the person performing CN quality control checks. The manufacturer will be required to resubmit their QC Program to the appropriate AMS Office for approval.

Manufacturers who switch from the IMP option to the QCVP option will begin at normal frequency. The manufacturer must fulfill all requirements for normal frequency to be eligible for reduced frequency. For example, if a manufacturer received satisfactory CN reviews for a year under the IMP option, the previous satisfactory reviews will not be considered part of the four (4) consecutive reviews required to qualify for reduced frequency. Manufacturers who switch from the QCVP option to the IMP option will be assigned an AMS/NMFS representative to monitor all shifts of CN product production.

4. Regular USDA/AMS or USDC/NMFS Services

For manufacturers currently receiving regular USDA/AMS or USDC/NMFS services, such as grading or commodity inspection, the in-plant grader or consumer safety officer can certify the further processing of donated items (as applicable) and can monitor production of CN labeled product(s) for compliance with CN Labeling requirements. However, the manufacturer may incur additional charges for the CN product review activities if the CN review extends beyond the AMS or NMFS personnel's normal tour of duty or additional staffing is needed.

Manufacturers receiving regular AMS and NMFS grading or inspection services are not required to participate in the IMP option. For example, the AMS grader is required to be present when a facility is processing a USDA commodity, however the production of CN labeled product may be monitored under the QCVP.

5. CN Plant Monitoring Review Checklist

The AMS and NMFS representative will use a standardized CN Plant Monitoring Review Checklist for both services (IMP and QCVP) to determine compliance with the CN Labeling requirements. The following are critical non-conformance categories outlined on the standardized checklist:

- Failure to provide the AMS or NMFS representative a copy of approved QC program during a CN product review, when requested.
- Use of an unapproved CN label (e.g. FNS draft instead of FNS approval or expired final or temporary label approval).
- Failure to monitor scales and measuring devices.
- Failure to monitor and control formulation.

- Failure to monitor and control percent fat content of CN product (as applicable).
- Failure to monitor and control weights (raw and cooked weights as applicable).
- Failure to monitor maximum cooking yield (as applicable).

MANUFACTURER'S RESPONSIBILITIES

1. Provide AMS or NMFS representative advance notice of CN production schedule.
2. Allow AMS or NMFS representatives into establishment(s) to perform the CN product review.
3. Provide a copy of their approved QC program, when requested by an AMS or NMFS representative.
4. Provide AMS and NMFS representatives any requested QC records generated as part of the CN Labeling program.
5. Implement and document corrective actions for all cited critical and non-critical non-conformances.
6. Halt production and/or restrict shipment of CN labeled product or divert product to non-CN if specifications are not met as written in approved QC program.

AMS AND NMFS RESPONSIBILITIES

1. Once the initial on-site review is complete, the approved QC manual will be returned to the manufacturer. The reviewer will not maintain copies of the approved QC manual past the initial on-site review.
2. Provide the manufacturer with a copy of the CN Plant Monitoring Review Checklist for each plant visit. The checklist will assist the manufacturer in monitoring their performance.
3. Submit a copy of the CN Plant Monitoring Review Checklist coversheet to the respective National Office through the appropriate channels.
4. Log and track results of each CN product review.

Table 3 - Facility Rating and Frequency Review